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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,449	03/24/2004	Karin Jooss	3802-090-27 CIP	3354
29585 7590 03/26/2008 DLA PIPER US LLP 153 TOWNSEND STREET SUITE 800 SAN FRANCISCO, CA 94107-1957			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 03/26/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/807,449

**Applicant(s)**

JOOSS ET AL.

**Examiner**

ILIA OUSPENSKI

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-43 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5, 9, 12-18, 21, 22 and 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6-8, 10, 11, 19, 20, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

1. Applicant's amendment and remarks, filed on 12/19/2007, are acknowledged.

Claim 2 has been canceled.

Claims 1 and 3 – 43 are pending.

Claims 3, 5, 9, 12 – 18, 21 – 22, and 25 – 43 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 11/21/2006.

***Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 are presently under consideration, as they read on the elected invention and species.***

The rejections of record can be found in the previous Office Action, mailed on 06/22/2007.

***The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.***

It is noted that the reference of Kjaergaard et al., provided by Applicant as Exhibit A, has been listed of record in the file of this application.

2. Claims 1, 4, 6 – 8, 10, 19 – 20, and 23 – 24 stand objected to as reading on non-elected embodiments of the invention, which are not under consideration in the instant application. Applicant is required to cancel the non-elected embodiments.

3. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

4. Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 stand rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The rejection is maintained for the reasons of record.

The specification does not provide a sufficient enabling description of a method for cancer therapy comprising administering a cellular vaccine.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the instant specification discloses examples of enhanced anti-tumor immunity achieved by administering proliferation-incompetent tumor cells that express GM-CSF.

In response, the disclosed examples appear to be prophetic rather than working examples. Given the unpredictability of the art of cancer therapy, and in particular with "vaccines," as addressed in the previous Office Action, such disclosure is not deemed to be sufficiently predictive of therapeutic outcomes. Thus, the experimentation left to those skilled in the art remains unnecessarily, and improperly, extensive and undue.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

5. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

*(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

6. Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 stand rejected under **35 U.S.C. 102(a) and 102(e)** as being anticipated by Chen et al. (US Pat. Pub. No. 2003/0035790), for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that claim 1, as amended, recites administration of tumor cells, which limitation allegedly it not taught by the reference.

This is not found persuasive, because Chen et al. teach i.e. in paragraph 0005 that in a cancer vaccine approach, cancer cells are isolated from patients, transduced with the relevant genes in vitro, made proliferation-incompetent by irradiation, and administered back to the patient to enhance the patient's immune response against the tumor.

Applicant further argues that the instant claims require administration of at least one additional therapeutic agent in combination with the cytokine-expressing cellular vaccine.

In response, Chen et al. teach administering anti-OX-40 antibodies together with the compositions of their invention (e.g. paragraphs 0041, 0117, 0120, and 0277).

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 stand provisionally rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 1 – 33 of copending Application USSN 10/404,662, for the reasons of record.

Applicant's request that this rejection be held in abeyance until the instant claims are indicated otherwise allowable is acknowledged.

Since the instant claims are not deemed to be allowable, the rejection is presently maintained for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Applicant's statement regarding **common ownership** of the instant application and USSN 10/404,664 is acknowledged.

**10. Conclusion: no claim is allowed.**

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI, Ph.D./

Primary Examiner, Art Unit 1644

March 22, 2008